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REMARKS

Claims 1-3 and 5-9 are pending in the application. Claims 1 and 7-9 are independent.

Claims 1-5 and 7-9 were finally rejected under 35 USC 103(a) as being unpatentable over Patent 6,416,533 (Gobin et al.); Claim 6 was rejected as being unpatentable over Gobin in view of US Patent 5,139,496 (Hed). Each of the rejections is respectfully traversed and reconsideration is requested.

Each of the independent claims, Claims 1, 7, 8 and 9, was previously amended to recite a system or method for changing the temperature of a patient, in which a single outlet lumen and an inlet lumen of a catheter are configured such that blood flows between the outlet lumen and the inlet lumen (see, at least, Figs. 2 and 3 of Applicant's specification as filed).

The Final Action states that "Gobin et al. teaches all of the limitations of the claims *except (1) a single output lumen, (2) the working fluid being saline and (3) an inflatable heat transfer element*" (numbers '1-3' not recited in Action, but added herein).

The Action then takes the position that it would have been obvious "to provide only a single outlet lumen, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art".

First, Applicant requests clarification as to the Examiner's assertion – i.e., how does the "omission of an element *and its function*" have the remaining elements "perform the same function" (if the function is omitted)?

A function of Applicant's single output lumen is, at least, to provide an outlet for the working fluid. The function of the "multiplicity of hollow fibers" of Gobin is to provide an outlet for the heat exchange fluid. Applicant's claimed catheter system does not 'omit the *function*' of Gobin's multiplicity of hollow fibers, but rather omits an element while retaining its function. As noted in MPEP 2144.04, the "omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966)"

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Gobin describes a catheter in which a "multiplicity of hollow fibers 198 can be disposed at the distal end 45 to define the heat exchange region 47 of the catheter 10" (col. 9, lines 51-62). The heat exchange fluid 85 flows distally along inner tube 190 into the distal manifold 194, and then "flows into the internal lumens of the hollow fibers 198 proximally to the proximal manifold 196". Gobin very specifically notes that the plurality of "hollow fibers 198 offer several advantages" in that they "provide a very high surface area between the blood 31 and the heat exchange fluid 85" (col. 9, lines 63-65). Therefore Gobin actually *teaches away from* a device as recited in Applicant's claimed invention, in which a *single* outlet lumen extracts a circulating working fluid.

The Action also takes the position that it would have been obvious "to provide a heat transfer element constructed of an inflatable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice".

Again Applicant respectfully disagrees with this alleged 'obvious' modification of the teachings cited. Applicant's specification notes that "a heat transfer element made of a flexible material *generally* has significantly *less* thermal conductivity than a heat transfer element made of metal", but that Applicant's device "compensates for this" by "*increasing the cross-sectional size and by increasing the length*" (see e.g. para [0064]). Gobin, on the other hand, teaches *away from* a modification to implement an inflatable material, in that Gobin notes that it would be desirable to provide a "*shorter and lower profile* heat exchange region" (col. 10, lines 3-7). It is not simply "selecting a known material on the basis of its suitability for the intended use", "as a matter of obvious design choice", when such a "choice" typically provides less thermal conductivity, and would require a longer length (which again, is *taught away from* in Gobin).

In view of the above discussion, the outstanding 103(a) rejections are believed to be improper and reconsideration is respectfully requested.

Since the Applicant has fully responded to the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Response After Final Rejection or of

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the application at large, request is made that the Examiner telephone the Applicant's undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,


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